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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/285,292 | 04/02/1999 | DONNA G. ALBERTSON | 023070-09140 | 3543 |
| 22798 | 7590 | 01/29/2008 | EXAMINER | |
| QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. | | | HARRIS, ALANA M | |
| P O BOX 458 | | | ART UNIT | PAPER NUMBER |
| ALAMEDA, CA 94501 | | | 1643 | |
| MAIL DATE | | DELIVERY MODE | | |
| 01/29/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 09/285,292 | ALBERTSON ET AL. | |
| | Examiner | Art Unit | |
| | Alana M. Harris, Ph.D. | 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 October 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 and 14-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 and 14-17 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/22/2007.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .

5) Notice of Informal Patent Application

6) Other: ____ .

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 22, 2007 has been entered.

2. Claims 1-12 and 14-17 are pending.

Claim 1 has been amended.

Claims 1-12 and 14-17 are examined on the merits.

New and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1-12 and 14-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Applicants reiterate the criteria for meeting the written description requirement, supply Google

results describing the CYP24 gene and assert the said gene and consequently the claimed method were adequately described, see page 5 of Remarks. These points of view, provided documents and arguments have been carefully reviewed and considered, but found unpersuasive.

While the Examiner notes the Google search of CYP24 gene provides enumerable "hits" and the gene is well established in the art, the crux of the issue is not that the gene is not well characterized and not established in the art, but how Applicants have defined the CYP24 gene in their specification. Information provided in the specification sets forth "CYP24 gene" is a DNA sequence that encodes a 24-hydroxylase enzyme...The term gene can refer to a mutated copy of the gene, or a fragment of the gene", see page 7, lines 10-12. It follows that the acronym CYP24 encompasses a genus of molecules, such as nucleic acids, proteins and mRNA that are not necessarily wild type forms of CYP24. The term reads on a plethora of variant, mutated and alternate forms of CYP24. Applicants have not described CYP24 with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. For the reasons of record and reiterated herein the rejection is maintained.

5. The rejection of claims 1-12 and 14-17 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting CYP24 mRNA in human breast tumor *in vitro* specimens treated with 1,25-dihydroxyvitamin D-3 comprising RT-PCR, does not reasonably provide enablement for a method of detecting

a predisposition to any cancer comprising detecting the level of *CYP24* nucleic acid or *CYP24* protein in a biological sample and comparing said level with the level from a control sample is maintained.

Applicants assert “[t]he specification teaches a number of methods of detecting the *CYP24* gene or protein product”, see page 7 of the Remarks, 4th paragraph. Applicants also note several peer-reviewed papers in support of their claimed invention. Applicants’ arguments have been carefully reviewed, but found unpersuasive.

The Examiner does not doubt the ability of one of ordinary skill in the art to detect *CYP24* mRNA and protein levels. Applicants are reminded the claims read on prevention and forecasting whether or not a person will develop cancer. This type of analysis is art known not to be an “exact science”. Moreover, the examples presented in the specification particularly note established breast cancer cell lines (MCF-7 and BT474). Clearly, it is known to those of ordinary skill in the art these cell lines are already deemed cancerous. Consequently, it is not clear how one of ordinary skill in the art would prevent breast cancer in a cell, and prevent the said cancer in a cell that has already been characterized. Hence, the specification is not commensurate with the scope of the claims. There is insufficient guidance in the specification providing methodology consistent with the claims. For the reasons of record and the reasons reiterated herein the rejection is maintained.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 9-12 and 15-17 are vague and indefinite because they do not recite how CYP24 protein is measured and what assays are required in quantization of the said protein. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced. The method steps should at least include reagents necessary for the assay, a detection step in which the reaction products are quantitated or visualized and a correlation step describing how the results of the assay allows the determination of for example, the detection of a disease.

b. Claim 1 is vague and indefinite because the preamble on lines 1 and 2 of the claim cite "...detecting...breast cancer", whereas the last line of section iii of the claim broadly cites "cancer". The preamble and the steps listed are not commensurate. Moreover, dependent claims 6, 9 and 11 also cite "cancer" broadly and are not further limiting.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER


Alana M. Harris, Ph.D.
05 January 2007